

U.S.S.N. 09/714,469
Filed: November 16, 2000
AMENDMENT

Allowance of claims 50-75 is earnestly solicited.

Respectfully submitted,



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Remarks

Copy of Abstract of JP6157878

The examiner has requested a copy of JP6157878. The only copy available to applicants is in Japanese and is undecipherable, at least to the undersigned. However, enclosed with this response is the published English abstract.

Rejections under 35 U.S.C. 112, second paragraph

The examiner has rejected claims 65 and 68 as indefinite for failing to describe the percent elongation in comparative terms. This rejection is respectfully traversed if applied to the amended claims.

The claims have been amended to insert the reference to "elongation at break" and the test conditions. Support is found in the examples, for example, at page 20, lines 10-14 and 26-28.

Rejections Under 35 U.S.C. § 102 or 103

Claims 64-75 were rejected under 35 U.S.C. 102(b) as disclosed by, or in the alternative, under 103(a) as obvious over, JP6157878A2. Applicants respectfully traverse these rejections.

JP6157878A2

The Japanese abstract refers to a composition having a high crystallization rate. This is the opposite of a material having a high elongation rate. Crystalline materials are typically brittle, not given to elongation without breaking. The material described in the Japanese reference is prepared by compounding a copolyester which includes 3HB. The total ratio of copolyester is 97-99.5%; the 3-HB makes up 85-97 mol% and 4-HB makes up the remaining 3-15 mol%. The composition is in the form of particles and further

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includes 0.5 to 3 wt% BN particles.

The Japanese patent application is representative of the prior art discussed at the top of page 15 of the application, which is characterized by brittleness and lack of elongation properties. This alone differentiates applicants' claimed materials and leads one away from using the combination of a PHA copolymer. However, the claims further distinguish over the Japanese application because applicants are claiming a blend. See, for example, page 15, lines 1-24. The Japanese application neither discloses nor leads one to make a composition which is not brittle and which can be elongated, but also fails to lead one to a polymer blend.

Claims 50-75 were rejected under 35 U.S.C. 103(a) as obvious over JP6157878A2 in combination with JP4-326932, JP6-336523, or U.S. Patent No. 5,753,782 to Hammond, et al. These rejections are respectfully traversed.

JP6157878A2

This application is discussed above. It teaches particles formed of a brittle, highly crystalline PHA. This would lead one skilled in the art away from the claimed compositions being capable of elongation.

JP4-326932 and JP6-336523

These applications are in Japanese. They have been cited for the principle of showing that 4HIB is a known polymer. See bottom of page 3 of the office action.

Hammond

Hammond has been cited for the use of 0.1 wt% nucleant such as boron nitride in a polyester such as a PHA like 3HIB or 4HB or PHBV. Hammond is directed to a polyester composition formed of a biodegradable polyester and a plasticising quantity of

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a plasticiser (col. 1, lines 28-42). The plasticiser is one of high-boiling organic molecules, phosphoric acid derivatives, phosphorous acid derivatives, or phosphonic acid derivatives (col. 1, lines 31-42). Hammond also provides that other **usual** materials such as a nucleant can be added to the composition (col. 6, lines 48-53). Therefore, the critical aspect of Hammond is the use of one or more of the plasticisers defined therein (col. 1, lines 28-42).

Hammond generally requires a polyester having units as defined at col. 2, lines 24-41. Preferred polyester is PHB or copolymer PHBV (col. 2, lines 36-37). Hammond does not specifically disclose poly(3-hydroxybutyrate-co-4-hydroxybutyrate).

Hammond does not teach a blend comprising PHB to produce a material with good elongation properties.

Hammond teaches away from a material not including a plasticizer. Hammond requires the use of one or more plasticisers to improve the processability of the polyesters defined therein (col. 1, lines 24-27). This critical element is clearly missing from the new claims. Yet, as shown in Examples 24-26 described on pages 33-34, the claimed polymer composition has excellent versatility, i.e., ductility, elongation rate, and aging characteristics (see Table 7). This clearly establishes that the new claims are non-obvious over Hammond (see, *In re Edge*, 359 F.2d 896, 149 USPQ 556 (CCPA 1966); see also MPEP § 2144.04(II)(B)).

Moreover, the fact that Hammond is directed to the use of a plasticiser to improve the processability of the polyester described therein indicate that Hammond does not provide one of ordinary skill in the art the motivation to make and use a polyester composition with no plasticiser. Even if one argued the Hammond did provide such as

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motivation, one would not have a reasonable expectation of success of the new claims because, as discussed above, the use of one or more plasticisers is critical to the composition described in Hammond. As such, Hammond would not render claims 50-75 *prima facie* obvious under 35 U.S.C. 103 (*see, Hodosh v. Block Drug Co., Inc.*, 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986); *see also* MPEP § 2141).

The Combination of the Japanese Patent Applications and Hammond

The prior art in combination does not lead one to the claimed invention. There is no teaching that a PHB blend, in combination with a nucleant, can have radically different properties. The first JPA teaches that a PHB including a nucleant is crystalline and therefore brittle, not elongatable. The two other JPAs teach only that PHB and PIIIV are known and nothing about the properties resulting from blending such materials. Hammond is no better. Hammond teaches that to alter the properties of the polymeric composition, one must include a plasticizer, not make a blend.

Accordingly, the prior art alone or in combination does not lead one to the claimed materials, methods of manufacture or use thereof.

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Appendix I: Clean Copy of Claims as Pending

50. (presently amended) A polymer composition comprising poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) blend and a nucleant with no plasticizer, wherein the percentage of 4-hydroxybutyrate (4HB) in the P3HB4HB is between 16% and 99%.
51. (unamended) The composition of claim 50 wherein the nucleant is boron nitride.
52. (unamended) The composition of claim 50 wherein the nucleant is present at levels between 0.1 and 20 wt% of the blend.
53. (unamended) The composition of claim 50 wherein the nucleant is present at levels between 1 and 10 wt% of the blend.
54. (presently amended) A method of producing a shaped polymeric object comprising melting a composition comprising a poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) blend wherein the percentage of 4-hydroxybutyrate (4HB) in the P3HB4HB is between 16% and 99% and a nucleant with no plasticizer, and producing a shaped object therefrom by extrusion, molding, coating, spinning, blowing, thermoforming or calendaring processes or combinations of the processes.
55. (unamended) The method of claim 54 wherein the nucleant is boron nitride.
56. (unamended) A shaped object made according to claim 54.
57. (unamended) A shaped object made according to claim 55.
58. (presently amended) A polymer composition comprising a poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) blend and a nucleant with no plasticizer, wherein the nucleant is present at a level of 0.1 wt% of the composition.

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59. (unamended) The composition of claim 58 wherein the nucleant is boron nitride.

60. (presently amended) A method of producing a shaped polymeric object comprising melting a composition comprising a poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) blend and a nucleant with no plasticizer, and producing a shaped object therefrom by extrusion, molding, coating, spinning, blowing, thermoforming or calendaring processes or combinations of the processes,

wherein the nucleant is present at a level of 0.1 wt% of the composition.

61. (unamended) The method of claim 60 wherein the nucleant is boron nitride.

62. (unamended) A shaped object made comprising the composition of claim 59.

63. (unamended) A shaped object made according to claim 60.

64. (presently amended) A polymer composition comprising poly-3-hydroxybutyrate-co-4-hydroxybutyrate (P3HB4HB) blend and a nucleant with no plasticizer wherein the composition is capable of forming a film having elongation,

65. (presently amended) The composition of claim 64 wherein the elongation at break is in the range between 560 % and 1100 % as measured by tensile testing on molded bars (5x2 mm section, 42 mm gauge length, 10 mm/min crosshead speed).

66. (unamended) The composition of claim 64 wherein the nucleant is present at a level between 0.1 and 20 wt% of the composition.

66. (unamended) The composition of claim 64 wherein the nucleant is present at a level between 1 and 10% of the composition.

67. (presently amended) A method of producing a shaped polymeric object comprising melting a composition comprising a poly-3-hydroxybutyrate-co-4-

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hydroxyutyrate (P3IIB4HB) blend and a nucleant with no plasticizer, and producing a shaped object therefrom by extrusion, molding, coating, spinning, blowing, thermoforming or calendaring processes or combinations of the processes,

wherein the composition is capable of forming a film having elongation.

68. (presently amended) The method of claim 67 wherein the elongation at break is in the range between 560 % and 1100 % as measured by tensile testing on molded bars (5x2 mm section, 42 mm guage length, 10 mm:min crosshead speed).

69. (unamended) The method of claim 67 wherein the nucleant is present at a level between 0.1 and 20 wt% of the composition.

70. (unamended) The method of claim 67 wherein the nucleant is present at a level of 1 to 10% of the composition.

71. (unamended) The method of claim 68 wherein the nucleant is present at a level between 0.1 and 20 wt% of the composition.

72. (unamended) The method of claim 68 wherein the nucleant is present at a level between 1 and 10% of the composition.

73. (unamended) The method of claim 67 wherein the nucleant is boron nitride.

74. (unamended) A shaped article made according to the method of claim 67.

75. (unamended) A shaped article made according to the method of claim 68.

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patrea, attached is webpage with abstract of 6157878A2 (also copied into the email below). there are no english equivalents listed. if you want a copy of the JP patent or if you can't open this page, just let me know. -erica

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Abstract

PURPOSE: To obtain a composition being excellent in impact and heat resistances and having biodegradability, biocompatibility and a high crystallization rate a compounding a specified polyester copolymer and a specified BN particles in a specified ratio.

CONSTITUTION: This resin composition comprises 99.5-97wt.% copolyester comprising 97-85mol% structural units derived from 3-hydroxybutyrate and 3-15mol% structural units derived from 4-hydroxybutyrate and 0.5-3wt.% BN particles having a particle diameter of 5-50µm.

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